

**REMARKS**

Claims 1, 2, 4-9, 11-23, and 25-35, as amended, are pending in this application for the Examiner's review and consideration. Applicant appreciates the courtesy extended to Applicant's attorney, Paul E. Dietze, in a telephonic interview held on August 21, 2003. The comments appearing herein are substantially in accordance with those presented and discussed during the interview. Claims 1 and 28-29 were amended to recite that the hydrophobic moisturizing agent and the hydrophilic moisturizing agent are present in an amount ranging from about 0.01 to 2 weight percent (*See, e.g.,* Specification, page 15, lines 2-5 and 12-14). Claims 1, 28, 29, and 33 were amended to delete the phrase "in an amount sufficient to exfoliate at least a portion of the patient's skin." Claim 33 was simply amended to move the recitation that the composition is orally administered after the transitional phrase. No new matter has been added by these claim amendments so that their entry at this time is warranted.

**THE DOUBLE PATENTING REJECTION**

Claims 1, 2, 4-9, 11-23, and 25-35 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of co-pending Application No. 09/501,218, now U.S. patent no. 6,630,163. Applicant will submit a Terminal Disclaimer, disclaiming the terminal part of any patent granted on the above identified application which would extend beyond the expiration date of U.S. patent no. 6,630,163, once all art rejections have been overcome.

**THE PENDING REJECTION UNDER 35 U.S.C. § 103(a)**

Claims 1, 2, 4-9, 11-23, 25-27, and 30-35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,985,300 to Crotty *et al.* ("Crotty") in view of U.S. Patent No. 5,891,440 to Lansky ("Lansky") and U.S. Patent No. 5,169,630 to Okaya *et al.* ("Okaya") for the reasons set forth on page 2-5 of the Office Action. Applicant respectfully traverses the rejection.

Crotty discloses a cosmetic product that is an adhesive strip to remove keratotic plugs and to deliver active ingredients to the skin (*See, e.g.,* Crotty, col. 2, lines 40-42). Crotty also teaches that a wetting agent, preferably water, is needed for the delivery of active ingredients to the skin (*See, e.g.,* Crotty, col. 5, lines 65 to col. 6, line 11).

Lansky discloses an oral or topical phytoestrogen supplement prepared from pomegranate material, *e.g.,* pomegranate seeds, and schizandra berries and Chinese asparagus

BEST AVAILABLE COPY

root (*See e.g.*, Lansky, col. 2, lines 49-56, and col. 3, lines 50-57). Lansky discloses an ointment prepared by pressing pomegranate seed to obtain oil and mixing the oil with coconut milk to form a mixture (*See e.g.*, Lansky, col. 3, lines 7-11). Lansky also discloses that the oral supplement or ointment may be administered to relieve various symptoms in menopausal women or postmenopausal women (*See e.g.*, Lansky, col. 3, lines 50-56).

Okaya discloses aqueous external skin preparations that contains Mn-SOD and/or modified Mn-SOD with improved reducing potential against skin-roughening by maintaining enzyme activity (*See, e.g.*, Okaya, column 1, line 67 to column 2, line 3).

The rejected claims are directed to the combination of (a) a hydrophobic moisturizing agent, (b) a hydrophilic moisturizing agent, and a (c) a mono- or poly-hydroxy acid and a fruit extract from pomegranate and manganese ascorbate (claim 1); a fruit extract from pomegranate and copper sebacate (claim 28); a fruit extract from pomegranate and a manganese compound, a copper compound, or a selenium compound in an orally administered formulation (claim 33); a fruit extract from pomegranate (claim 34); or a fruit extract and a transition metal component (claim 35).

None of the references cited by the Examiner disclose or suggest combining each of a hydrophobic moisturizing agent, a hydrophilic moisturizing agent, and a mono- or poly-hydroxy acid in a single composition with the other components of the formulation (*See, e.g.*, Specification, page 15, lines 19-25). The acidic component moisturizer functions by removing the dead or dying skin cells, enabling the skin to better absorb moisture from the atmosphere (*See e.g.*, Specification, page 15, lines 19-25). The hydrophobic agents prevent the loss of water from the skin (*See e.g.*, Specification, page 15, lines 19-25). The hydrophilic agents moisturize the skin by absorbing moisture or facilitating hydration of the skin (*See e.g.*, Specification, page 15, lines 19-25).

The combination of a hydrophilic moisturizer, a hydrophobic moisturizer, and a mono- or poly-hydroxy acid is an important feature of the invention. A composition comprising a combination of a hydrophilic moisturizer, a hydrophobic moisturizer, and a mono- or poly-hydroxy acid improves the efficacy of the other components (i.e., the fruit extract from pomegranate and manganese ascorbate (claim 1); the fruit extract from pomegranate and copper sebacate (claim 28); the fruit extract from pomegranate and the manganese compound, copper compound, or selenium compound in an orally administered formulation (claim 33); the fruit extract from pomegranate (claim 34); or the fruit extract and the transition metal component (claim 35)) and, accordingly, is superior at treating a dermatological disorder compared to compositions that do not include all three of a

hydrophilic moisturizer, a hydrophobic moisturizer, and a mono- or poly-hydroxy acid. Presumably, a composition comprising the combination of all three components is unexpectedly superior at treating a dermatological disorder compared to either component alone due to a synergistic effect. This unexpected advantage of the combination is not disclosed or suggested in the references cited by the Examiner.

As evidence of the unexpected results Applicant, submits herewith a Declaration by Dr. Howard Murad, one of ordinary skill in the art ("the Murad Declaration"). The Murad Declaration, includes two case studies that clearly illustrate the unobvious, surprising, and unexpected results obtained with the claimed compositions that comprises each of a hydrophilic moisturizer, a hydrophobic moisturizer, and a mono- or poly-hydroxy acid (See, e.g., Murad Declaration, ¶4).

The two case studies, which are representative, clearly show that the combination is superior at managing dermatological conditions compared to the individual components (See Murad Declaration, ¶4). In the first case study, topical administration of pomegranate extract and ceramide (a hydrophobic moisturizing agent) to a patient with severe case of sun damaged and aged skin was ineffective. Administration of pomegranate extract, ceramide (a hydrophobic moisturizing agent), sodium peroxylinecarboxylic acid (sodium PCA) (a hydrophilic moisturizing agent), hyaluronic acid (a hydrophilic moisturizing agent), and glycolic acid (a mono- or poly-hydroxy acid), i.e., the composition of the invention, however, resulted in improved elasticity of the patients skin, a reduction in wrinkles, and led to tighter and smoother facial skin (See Murad Declaration, ¶4).

In the second case study, 5 individuals were first treated with a facial mask containing an extract of pomegranate and ceramide (a hydrophobic moisturizing agent) and then with a mask containing a combination of pomegranate extract, ceramide (a hydrophobic moisturizing agent), hyaluronic acid (a hydrophilic moisturizing agent), and glycolic acid (a mono- or poly-hydroxy acid) i.e., the composition of the invention. Treatment using the composition of the invention, i.e., with the combination of pomegranate extract, ceramide, hyaluronic acid, and glycolic acid led to superior skin appearance, skin tone, elasticity, and pigmentation. These clinical observations clearly show the surprising and unexpected results of the invention (See, e.g., Murad Declaration, ¶ 4 and 5).

Applicant respectfully submits that the Examiner is impermissibly using hindsight to reconstruct Applicants invention. The Examiner is picking and choosing the specific components of Applicant's invention from a broad disclosure of components, in several references, some directed to oral administration and others directed to topical

administration, with no motivation to choose the claimed components, to arrive at Applicant's invention. Specifically, there is absolutely no suggestion in the prior art to combine a hydrophilic moisturizer, a hydrophobic moisturizer, and a mono- or poly-hydroxy acid, as presently claimed.

Hindsight cannot be used to reject a claim as obvious. *In re Sernaker*, 702 F.2d 989, 994 (Fed. Cir. 1983); *In re Rinehart*, 531 F.2d 1048 (CCPA 1976); *In re Imperato*, 486 F.2d 585 (CCPA 1973); *In re Adams*, 356 F.2d 998 (CCPA 1966). Consequently, it is legally improper to select from the prior art the separate components of the inventor's combination, using the blueprint supplied by the inventor. *C.R. Bard Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998) citing *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985) (holding the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination). Indeed, the Federal Circuit has suggested that "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or modification to combine prior art references." *Id.* This is because "when prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1142 (Fed. Cir. 1985).

In the present case, there is absolutely no suggestion in the prior art to combine each of (a) a hydrophobic moisturizing agent, (b) a hydrophilic moisturizing agent, and (c) a mono- or poly-hydroxy acid with a fruit extract from pomegranate and manganese ascorbate (claim 1); a fruit extract from pomegranate and copper sebacate (claim 28); a fruit extract from pomegranate and a manganese compound, a copper compound, or a selenium compound (claim 33); a fruit extract from pomegranate (claim 34); or a fruit extract and a transition metal component (claim 35).

Moreover, even if there was a motivation to combine the references, which Applicant respectfully submits there is not for the reasons stated above, there is no reasonable expectation that the combination of a hydrophobic moisturizing agent, a hydrophilic moisturizing agent, and a mono- or poly-hydroxy acid with the other recited components of the claimed composition, would provide a composition that improves the efficacy of the other components in treating a dermatological condition. Clearly, none of the references disclose or suggest the claimed amounts of the hydrophilic and hydrophobic moisturizing agent.

Furthermore, the combination of Crotty, Lansky, and Okaya does not disclose the orally administered formulations disclosed in claim 22 and independent claim 33. Crotty and Okaya are each directed to *topically* applied compositions. Applicant respectfully submits that one of ordinary skill in the art would not have been motivated to combine Crotty (directed to adhesive strips) and Okaya (directed to external skin preparations) with Lansky to render obvious *oral* compositions, such as recited in claim 22 and independent claim 33. Clearly, an adhesive strip as disclosed in Crotty would not be combined with an *oral* formulation as disclosed in Lansky. See M.P.E.P. § 2143.01. Further, Okaya only discloses external skin preparations and, accordingly, cannot be combined with Lansky to disclose or suggest the *oral compositions* of claim 22 and independent claim 33. Accordingly, claims 22 and 33 directed to oral compositions are not rendered obvious by the cited references.

For the above reasons, Applicant respectfully requests that the rejection of claims 1, 2, 4-9, 11-23, 25-27, and 30-35 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Claim 28 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Crotty in view of Lansky and further in view of U.S. Patent No. 5,759,555 to Moy ("Moy") for the reasons set forth on page 5-6 of the Office Action. Applicant respectfully traverses the rejection.

Moy discloses methods for ameliorating stretch marks and keratoses by applying to the affected skin a dermatological composition comprising unsaponifiable lipids extracted from avacodo seeds (See, e.g., column 2, lines 55-63).

There is, however, no suggestion in Crotty, Lansky, or Moy to use all three of a hydrophilic moisturizer, a hydrophobic moisturizer, and a mono- or poly-hydroxy acid in a composition that further comprises copper sebacate and a fruit extract from pomegranate, as presently recited in claim 28, or the unexpected effects of the combination, as discussed above. Applicant respectfully submits that the Examiner is again impermissibly using hindsight to select from the prior art the separate components of the inventor's combination using the blueprint supplied by the inventor to arrive at Applicant's invention. For the above reasons, Applicant respectfully requests that the rejection of claim 28 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Claims 29 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Crotty in view of Lansky and further in view of U.S. Patent No. 5,804,167 to Schonrock ("Schonrock") for the reasons set forth on page 6-7 of the Office Action. Applicant respectfully traverses the rejection.

Schonrock discloses emulsifier free finely dispersed formulations of the water in oil type (*See, e.g.*, Schonrock, column 2, lines 9-11).

The Examiner acknowledges that Crotty and Lansky fail to disclose selenium complexed with an amino acid and cites Schonrock for disclosing selenium complexed with an amino acid. Again, Applicant respectfully submits that the mere disclosure of a composition that includes selenium complexed with an amino acid does not render claim 29 obvious. There is absolutely no disclosure or suggestion in Crotty, Lansky, or Schonrock to combine each of a hydrophobic moisturizing agent, a hydrophilic moisturizing agent, and a mono- or poly-hydroxy acid (or the unexpected advantages of such a combination, discussed above) with a fruit extract from pomegranate, much less with selenium complexed with an amino acid, as recited in claim 29. Again, Applicant respectfully submits that the Examiner is impermissibly using hindsight to select from the prior art the separate components of the inventor's combination using the blueprint supplied by the inventor to arrive at Applicant's invention. For the above reasons, Applicant respectfully requests that the rejection of claim 28 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

All claims are believed to be in condition for allowance. Should the Examiner disagree, Applicant respectfully invites the Examiner to contact the undersigned attorneys for Applicant to arrange for an interview in an effort to expedite the prosecution of this matter.

No fee of is believed to be due for this submission. Should any fees be required, however, please charge the required fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date October 15, 2003



Paul E. Dietze  
For: Victor N. Balancia

(Reg. No. 45,627)  
(Reg. No. 31,231)

**PENNIE & EDMONDS LLP**  
1667 K Street, N.W.  
Washington, DC 20006  
(202) 496-4400

Enclosures